Design and Implementation of a Biosurety Program at the University of California for High-Containment Research Laboratories

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University of California High-Containment Lab Initiatives
2014 - 2022

Topics-
- BSL-3 Laboratories – The Basics
- The Charge
- Structure & Governance of UC Program
- BSL-3 Training Program
- Successes, Challenges & Next Steps
- Current Status & Research
- Resources and References

Biosafety Level 3 - Basics

Laboratory Practices & Procedures

High-Containment Facility

BSL-3 (High-Containment) Laboratory

Primary Barriers / PPE

Biological Safety Cabinet

Containment equipment

- sealed centrifuges
- secondary containers for transport

PPE

respirators (PAPR/N95), double gloves, solid front gowns/Tyvek, shoe covers

Secondary Containment / Facility Features

Separate, isolated facility

Anteroom for gowning

Dedicated HVAC exhaust

Directional airflow into lab

HEPA filtration of exhaust

Single pass air

HVAC isolation dampers

Laboratory biosecurity

Sealed penetrations

Easily cleanable surfaces

Failure alarms

Effluent decon procedures

Annual testing & Performance verification

Why the focus at UC ?

CDC: Up to 86 workers possibly exposed to anthrax (CNN June 27, 2014)

C.D.C. Closes Anthrax and Flu Labs After Accidents (New York Times, July 11, 2014)

Vials of Smallpox Found in F.D.A. Storage Room (New York Times July 8, 2014)

FDA found more than smallpox vials in storage room (Washington Post, July 16, 2014)

Smallpox find was among hundreds of other long-lost vials, FDA says (LA Times, July 16, 2014)

University of California

New UC President - Janet Napolitano

Former Head of DHS

Prompted evaluation of BSL-3 program

Emphasize safety and consistency

Establish policies and minimum guidelines

Integrate Biosafety & Biosecurity

UC High-Containment Lab Initiatives – Task Force

2014

Biosafety / Biosecurity Task Force

5 Faculty
1 Campus Vet
2 High-Cont.Specialists,
2 BSO's
2 Legal
1 AVC
3 OP Staff (EH&S, Compliance, Research)

Submitted 39 recommendations

Survey
Best Practices
Training
Inventory, Oversight, Security
Design, Construction
Commissioning, Decommissioning

All Recommendations Accepted by President Napolitano (2015)

UC High-Containment Lab Initiatives – Key Objectives

2015

President's Communication

- Establish System-wide High-Containment Lab Oversight Committee
- Establish Campus High-Containment Lab Oversight Groups
- Establish High-Containment Lab Director/Officer positions
- Provide High-Containment Lab Directors Training
- Perform BSL-3 Lab Site-Surveys
- Conduct RG3 Materials Inventory

UC High-Containment Lab Initiatives – Structure & Governance

UC HCLOC (Systemwide)

- Review Biosafety / Biosecurity Reports
- Resource for construction, repair, retrofit
- Implement Task Force findings
- Review campus HCLOG activities on an annual basis

HCLOG (Campus)

- Advise, plan, & review operations and maintenance
- Review and advise on retrofits, upgrades, & equipment
- Review safety plans, training, waste management and incident response preparedness
- Evaluate facility testing, validation and commissioning

Institutional Biosafety Committee (Campus)

- Review research protocols for Biosafety and Biosecurity
- Conduct Risk Assessments
- Evaluate work practices, disinfection methods, inactivation verification methods, etc.
- Approve protocols, training

UC High-Containment Lab Initiatives-
High-Containment Lab Directors - HCLDs

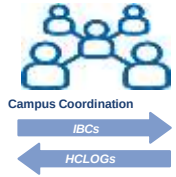
High-Containment Laboratory Director/Officer positions

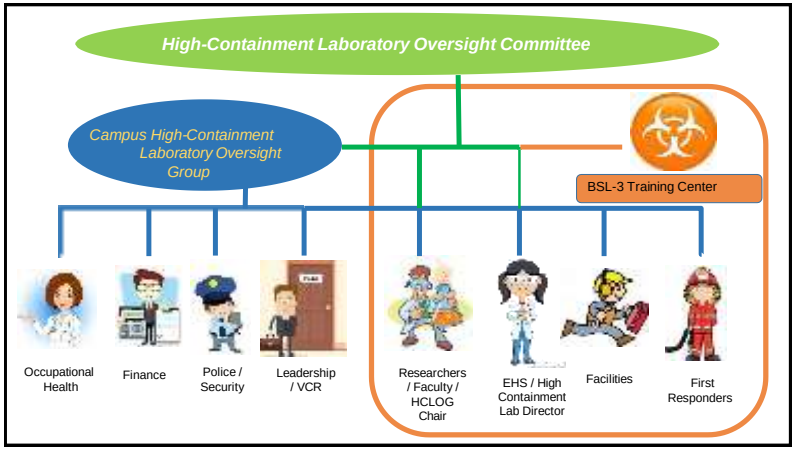
- Design, develop and implement High-Containment Lab Safety Program
- Oversee HCL operations & maintenance
- Work with Everyone to develop and implement policies and procedures
- Conduct facility inspections and program audits
- Ensure researchers, facility staff, responders have training
- Advise architects and engineers on plan design
- Plan and support incident response drills
- Respond and provide support during emergencies
- Support and maintain necessary documentation

HCLD's in 2018

UC High-Containment Lab Initiatives –
HCLD / HCLOG vs BSO / IBC

HCLD/HCLOG	BSO/IBC
Facility Inspection, Verification Testing & Risk Assessment	Laboratory Inspection, Research Risk Assessment
BSL-3 Site-Specific Training	General Training
Occupational Health Clearance	Occupational Health
BSL-3 Emergency Response	Formal Approvals
Facility Design/Renovation	Agent Specific Work Practices/PPE/Training Requirements
Operation Maintenance, Security, Finance	Inactivation Verification
Standardize Work Practices/PPE/SOPs	





BSL- 3 Laboratory Design Standards - Overview

References and Resource Documents:

- CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition 2009, 6th Edition 2020
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), 2016
- NIH Design Requirements Manual for Biomedical Laboratories and Animal Research Facilities (DRM), 2019
- National Institutes of Health Biosafety Level 3 Laboratory Certification Requirements, 2006
- ANSI Z9.14 - BSL-3/ABSL-3 Laboratory Verification 2014, 2020

BSL- 3 Laboratory Training Standard - Overview

UC HCLD – Workgroup Project

CDC Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition 2009, 6th Edition 2020

UC Resources:IBCs, IACUCs, High-Containment Lab Oversight Groups, UC Office of the President High-Containment Lab Oversight Committee

UCI National BSL-3 Training Program

Approved 2021

UC Irvine BSL- 3 National Training Center

Training Program

2015 UC BSL-3 Biosafety Training Program (initiated 2006)

- Dedicated BSL-3 training lab, NIH Designated Training Center
- UC-CoE since May 2015, no-fee registration for all UC personnel
- Over 375 UC BSL-3 lab associated personnel trained
- 14 UC High-containment Lab Directors trained
- Over 3000 trained nationally (since 2006)
- Courses presented at UCI & on-site at remote locations

UCI National BSL-3 Training Program

BSL-3 Training Program Courses:

Researcher Program
(Foundation, Initial & Refresher)

Operations & Maintenance
(Introductory, Intermediate, Annual Refresher)

Emergency First Responders

Certified Trainer Program

BSL-3 Testing & Validation (ANSI Z9.14)

CEUs & ABSA CMUs

- Microbiology and biosafety
- Biocontainment laboratory architecture and design
- Biosafety and biocontainment
- Emerging issues in biosafety and biocontainment
- Fundamentals of laboratory mechanics
- Laboratory commissioning and certification
- Laboratory sterilization and disinfection
- Laboratory systems: Continuity of operations planning
- Laboratory systems: Utilities and maintenance
- Troubleshooting laboratory HVAC, filtration and utility systems
- Personal protective equipment (PPE) selection and use
- Emergency management for BSL-3
- BSL-3 Biosecurity and the select agent program
- BSL-3 Laboratory validation principles
- ANSI Z9.14 BSL-3 Laboratory Verification Standard
- BSL-3 Laboratory Decommissioning

UC High-Containment Lab Initiatives - Summary

Challenges

Authority of the systemwide HCLOC

Coordination between campus HCLOG and IBC

Defining HCLD roles and responsibilities

Supporting O&M programs

Coordination with Medical Center activities

Consensus and application of BSL-3 design criteria

Funding opportunities

UC High-Containment Lab Initiatives - Summary

Successes

- Campus BSL-3 Annual Budget Models
- Standardized Training Requirements
- Checklists for Decommissioning
- Annual Facility Verification Recommendations
- BSL-3 Lab Design Standard
- Campus Location Consistency
- Unified Resources

UC High-Containment Lab Initiatives

Current UC High-Containment Research Activities

- Facilities at 8 different campuses, 5 Medical Centers
- Thirty five active research labs (3 more in progress)
  - Animal facilities
  - Insectaries
  - Plant facilities
- Multiple Select Agents
- Approximately 335 researchers
- Medical Center Clinical Diagnostic Labs

UC High-Containment Lab Initiatives

Resources and References

UC High Containment Laboratory Oversight Committee

https://www.ucop.edu/safety-and-loss-prevention/environmental/groups/hcloc/index.html

UC HCLOC Charter

https://www.ucop.edu/safety-and-loss-prevention/_files/groups/uchcloc_charter.pdf

UC BSL-3 Training Standard

https://www.ucop.edu/safety-and-loss-prevention/_files/hcloc/uc-bsl3-training-standard.pdf

UCI BSL-3 Training Center – Courses and Services

http:/som.uci.edu/bsl3-training

UC BSL-3 Lab Design Standard

https://www.ucop.edu/safety-and-loss-prevention/environmental/groups/hcloc/bsl-3-laboratory-design-standards.html

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Questions ???